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	T0	T1 Month	T2 Months	T3 Months	T6 Months
1 mg/mL Hydromorphone in Oxygen Barrier Packaging - RRT 0.72 Impurity Content Storage - 40° C./75% RH					
Standard packaging	0	N/A	N/A	0.090	0.240
O ₂ Barrier Packaging	0	N/A	N/A	0.080	0.070
10 mg/mL Hydromorphone in Oxygen Barrier Packaging - Pseudo morphine Content Storage - 40° C./75% RH					
Standard packaging	0	N/A	N/A	0.080	0.190
O ₂ Barrier Packaging	0	N/A	N/A	0.040	0.030

FIG. 16 is a graphical representation of the results in the previous table. FIG. 16 (top) shows storage of 1 mg/mL hydromorphone (HYD) formulations in standard and oxygen barrier packaging at accelerated conditions (40° C./75% RH) for six months. The graph shows that the 1 mg/mL hydromorphone formulation in standard packaging had an unacceptable unknown impurity (RRT 0.72) at the end of the six month storage period. FIG. 16 (bottom) storage of 10 mg/mL hydromorphone formulations in standard and oxygen barrier packaging at accelerated conditions (40° C./75% RH) for six months. At the end of the six month period in accelerated conditions, the hydromorphone formulations in standard packaging was very close to the specification limit for the unknown impurity (RRT 0.72). The 1 mg/mL and 10 mg/mL hydromorphone formulations in oxygen barrier packaging were stable with impurity levels stable and below the specification limits.

Promethazine

The stability of 25 mg/mL promethazine formulations were examined in standard packaging (i.e., without oxygen barrier secondary packaging and/or oxygen absorber) and in oxygen barrier packaging (i.e., with oxygen barrier secondary packaging and oxygen absorber) at ambient (25° C./60% RH) for 24 months and accelerated conditions (40° C./75% RH) for six months.

The following tables show that in both ambient and accelerated conditions, the sulfoxide impurity content in the promethazine formulations with oxygen barrier packaging were under the specification limits whereas the promethazine formulations with standard packaging quickly had unacceptable levels (0.2% or higher) of the sulfoxide impurity:

25 mg/mL Promethazine in Oxygen Barrier Packaging - Sulfoxide Content Storage - 25° C./60% RH							
	T0	T3 Months	T6 Months	T9 Months	T12 Months	T18 Months	T24 Months
Standard packaging	0.17	0.67	1.21	N/A	1.55	0.21	0.30
O ₂ Barrier Packaging	0.12	0.17	0.17	N/A	0.13	N/A	0.032

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25 mg/mL Promethazine in Oxygen Barrier Packaging - Sulfoxide Content Storage - 40° C./75% RH					
	T0	T1 Month	T2 Months	T3 Months	T6 Months
Standard packaging	0.173	0.451	N/A	0.854	1.46
O ₂ Barrier Packaging	0.12	0.177	0.114	0.104	0.12

FIG. 17 is a graphical representation of the results in the previous table. FIG. 17 (top) shows storage of 25 mg/mL promethazine (PRZ) formulations in standard and oxygen barrier packaging at ambient conditions (25° C./60% RH) for twelve months. The graph shows that the promethazine formulation in standard packaging had an unacceptable levels of sulfoxide by the three-month assay point which continued to increase to the end of the storage period. The promethazine formulation in oxygen barrier packaging had sulfoxide impurity levels under the specification limits. FIG. 17 (bottom) storage of 25 mg/mL promethazine formulations in standard and oxygen barrier packaging at accelerated conditions (40° C./75% RH) for six months. At the one-month assay point, the promethazine formulations in standard packaging already exceeded the specification limit for sulfoxide. The promethazine formulations in oxygen barrier packaging were stable with sulfoxide impurity levels stable and below the specification limits.

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A pharmaceutical packaging system for an injectable oxygen-sensitive drug, the packaging system comprising:
 - (i) a syringe filled under inert conditions with an injectable oxygen-sensitive drug, wherein the syringe has an oxygen permeable tip cap and wherein the oxygen-sensitive drug is one of morphine, hydromorphone, and promethazine;
 - (ii) a hermetically sealed oxygen barrier blister packaging which houses the syringe, wherein the blister packaging

comprises a multilayer bottom web comprising ethylene vinyl alcohol (EVOH) and a multilayer top web lid comprising aluminum foil or EVOH; and

- (iii) an oxygen absorber, wherein the oxygen absorber reduces the oxygen level present from the time of pack-